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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/870,521	06/01/2001	Marcia M. Miller	1954-310	1318

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EXAMINER

WHISENANT, ETHAN C

ART UNIT PAPER NUMBER

1634

DATE MAILED: 01/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/870,521

Applicant(s)

MILLER ET AL.

Examiner

Ethan Whisenant, Ph.D.

Art Unit

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-20 is/are pending in the application.
- 4a) Of the above claim(s) 19 and 20 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 5-6 is/are allowed.
- 6) ☒ Claim(s) 1-4, 7 and 8 is/are rejected.
- 7) ☐ Claim(s) 9-18 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

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## DETAILED ACTION

1. Applicant's election of Group I (**Claims 1-18**) in Paper No. 8 is acknowledged. Claims 19-20 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention. It is noted that the applicant has not traversed the restriction requirement, distinctly and specifically pointing out any supposed errors in the restriction requirement, therefore, this election has been treated as an election without traverse (MPEP § 818.03(a)). The restriction requirement has been reconsidered, is deemed proper and is therefore, herein made **FINAL**.

## SEQUENCE RULES

2. This application complies with the sequence rules and the sequences have been entered by the Scientific and Technical Information Center.

## 35 USC § 112 - 1ST PARAGRAPH

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

## CLAIM REJECTIONS under 35 USC § 112- 1ST PARAGRAPH

4. **Claims 1-4, 7-8** are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for an isolated polynucleotide comprising at most 626 nucleotides as set forth in SEQ ID NO: 1 or at most 675 nucleotides as set forth in SEQ ID NO: 2; does not reasonably provide enablement for the entire chromosome on which the gene(s) of the instant invention reside. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected to make the invention commensurate in scope with these claims without undue experimentation.

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In *In re Wands*, 858 F.2d 731,737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988) the court considered the issue of enablement in molecular biology. The Court summarized eight factors to be considered in a determination of "undue experimentation". These factors include: (a) the quantity of experimentation necessary; (b) the amount of direction or guidance presented; (c) the presence or absence of working examples; (d) the nature of the invention; (e) the state of the prior art; (f) the relative skill of those in the art; (g) the predictability of the art; and (h) the breadth of the claims. The Court also stated that although the level of skill in molecular biology is high, results of experiments in molecular biology are unpredictable.

To begin, there is no direction or guidance presented as regards the sequence of the entire chromosome beyond SEQ ID. NOs: 1 and 2. While the relative skill in the art is very high (the Ph.D. degree with laboratory experience), there is no predictability as to what sequences are present on the claimed chromosome beyond that portion of the chromosome set forth in SEQ ID NOs: 1 and 2.

As regards the nature of the invention, the claimed invention is drawn to polynucleotides. Polynucleotides are a chemical compound with an exact nucleotide sequence and claims drawn to polynucleotides should clearly define the nucleotide sequence for which protection is desired. The breadth of these claims includes any polynucleotide sequence - including an entire human chromosome - which comprises SEQ ID NO: 1 and/or SEQ ID NO: 2. Accordingly, it is concluded that undue experimentation is required to make the invention as it is claimed. See M.P.E.P. §§ 706.03(n) and 706.03(z).

### 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that may form the basis for rejections set forth in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) The invention was described in --

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a)

**Claim Rejections under 35 USC § 102**

- 6.** Claim(s) 1-4 and 11 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Shiina et al. (May 1999).

Shiina et al. teach a probe comprising at least about 17 consecutive nucleotides of SEQ ID NO: 1 and which comprises at least about 17 to about 1000 nucleotides. See the attached sequence comparison labeled "SEQ ID NO: 1/ Shiina et al." In addition, Shiina et al. teach a probe comprising at least about 17 consecutive nucleotides of SEQ ID NO: 2 and which comprises at least about 17 to about 1000 nucleotides. See the attached sequence comparison labeled "SEQ ID NO: 2/ Shiina et al." Note that the probe(s) taught by "SEQ ID NO: 2/ Shiina et al." is at least about 70% homologous to the probe of Claim 6.

- 7.** Claim(s) 3-4 is/are rejected under 35 U.S.C. 102(e) as being anticipated by Bacon et al. [US 6, 075,125 (JUN 2000)].

Bacon et al. teach a probe comprising at least about 17 consecutive nucleotides of SEQ ID NO: 2 and which comprises at least about 17 to about 1000 nucleotides. See the attached sequence comparison labeled "SEQ ID NO: 2/ Bacon et al."

- 8.** Claim(s) 3-4 and 11 is/are rejected under 35 U.S.C. 102(b) as being anticipated by Chaussé et al. [FR2771422 (28 MAY 1999)].

Chaussé et al. teach a probe comprising at least about 17 consecutive nucleotides of SEQ ID NO: 2 and which comprises at least about 17 to about 1000 nucleotides. See the attached sequence comparison labeled "SEQ ID NO: 2/ Chaussé et al."

#### CLAIM OBJECTIONS

**9.** Claim(s) 7-12, and 14 is/are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

**10.** Claim(s) 13 and 15-18 is /are objected to because they are dependent upon rejected independent base claims (i.e. 1 and 3).

#### CONCLUSION

**11.** Claim(s) 5-6 is/are allowable while Claim(s) 1-4 and 7-18 is/are rejected and/or objected to for the reason(s) set forth above.

**12.** Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ethan Whisenant, Ph.D. whose telephone number is (703) 308-6567. The examiner can normally be reached Monday-Friday from 8:30AM -5:30PM EST or any time via voice mail. If repeated attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached at (703) 308-1152.

The fax number for this Examiner is (703) 746-8465. Before faxing any papers please inform the examiner to avoid lost papers. Please note that the faxing of papers must conform with the Notice to Comply published in the Official Gazette, 1096 OG 30 (November 15, 1989). Any inquiry of a general nature or relating to the status of this application should be directed to the group receptionist whose telephone number is (703) 308-0196.



Ethan Whisenant, Ph.D.  
Primary Examiner